

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Katherine Lobel-Rice on 09/22/09.

The application has been amended as follows:

In claim 20, line 7, after "2 seconds or less" insert --wherein the device produces a condensation aerosol containing about 10% or less by weight drug composition degradation products and at least 50% of the drug composition of said film-- .

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The prior art teach preparing, devices for and administering aerosol compositions comprising various active agents such as alprazolam, buprenorphine, donepezil, sumatriptan, zolpidem, etc, with an MMAD of less than 5 micron. The novelty in the instant Application lies within the device producing and administering condensate aerosols. The prior art does not teach the process of heating, vaporizing and cooling the compounds to prepare condensates of the drug particles. Also such condensates provide a degradation product of less than 10% or preferably less than 5% for the

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particles, an MMAD of less than 5 micron and a geometric standard deviation of less than 3.

With regards to the Obviousness Double Patenting rejections over the co-pending applications comprising different active agents, Applicants have argued that each drug has to be individually examined and tested to determine suitability for the said process of heating and volatilizing. In other words, Applicants have argued that the ability of a drug to be dispensed according to the present invention is unpredictable. And, that some actives tested failed, while others worked. In view of said arguments and further in view of the terminal disclaimers filed on 09/08/09, the instant claims are found unobvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*/Mina Haghighatian/*

Mina Haghighatian  
Primary Examiner  
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